



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/648,811	08/25/2003	Paul A. Price	407T-895413US	5266

22798 7590 06/15/2006

QUINE INTELLECTUAL PROPERTY LAW GROUP, P.C.
P O BOX 458
ALAMEDA, CA 94501

EXAMINER

NGUYEN, BAO THUY L

ART UNIT PAPER NUMBER

1641

DATE MAILED: 06/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/648,811

Applicant(s)

PRICE ET AL.

Examiner

Bao-Thuy L. Nguyen

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 101

1. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

2. Claims 1 and 3 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claimed antibody is not recited as being an isolated product.

It is recommended that the claim be amended as follows:

Claim 1. An isolated antibody that specifically binds YKL-40.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

A person shall be entitled to a patent unless -

4. Claims 1 and 3 are rejected under 35 U.S.C. 102(a) as being anticipated by Johansen et al (Abstract for Scientific Conference. Davos, Switzerland. Published on or after July 12, 1992) in light of Johansen et al (British Journal of Rheumatology. 1993. Vol. 32, No. 11, pages 949-955).

The Johansen abstract discusses the discovery of YKL-40 and specific radioimmunoassay for the same. The abstract did not list the reagents of the radioimmunoassay. However, in a post filing date reference, Johansen discusses the specific reagents that are necessary for a radioimmunoassay of YKL-40, including a polyclonal antibody that binds specifically thereto. See page 950.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Johansen (in light of Johansen) in view of Maurer et al (Methods in Enzymology. Vol. 70, pages 49-70. 1980).

See the discussion of Johansen above. Johansen differs from the instant claims in failing to teach a monoclonal antibody specific for YKL-40.

Maurer, however, discloses methods of making polyclonal and monoclonal antibodies to many different antigens and

Therefore, one of ordinary skill in the art would have had an extremely reasonable expectation of success in producing a monoclonal antibody to the YKL-40 of Johansen

Art Unit: 1641

using the method taught by Maurer because the use of a monoclonal antibody to YKL-40 is of unquestioned research and interest and one of ordinary skill in the art would have had a reasonable expectation of success at generating monoclonal antibodies reactive with YKL-40 due to the teachings that this protein is immunogenic and that immunization of mice or other laboratory animals with various immunogenic YKL-40 antigens, in conjunction with notoriously old and well known fusion techniques, achieves the expected result, i.e. the production of monoclonal antibodies reactive with said YKL-40 antigens.

7. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Johansen (in light of Johansen) in view of Olsen et al (WO 90/08195).

See the discussion of Johansen above. This reference differs from the instant claim in failing to teach a labeled antibody.

Olsen discloses labeled monoclonal antibodies to human Type IX collagen and human c(IX) collagen chains. Olsen teaches that monoclonal antibodies can be labeled by any conventional procedure with any suitable label and employed in a conventional assay procedure such as ELISA and radioimmunoassay. See page 7, lines 14-24.

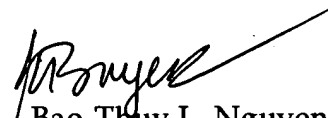
It would have been obvious to one of ordinary skill in the art at the time the invention was made to label the antibody of Johansen such as taught by Olsen because labeling techniques are disclosed as well known and conventional in the art.

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Tuesday and Wednesday from 8:00 a.m. -4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Bao-Thuy L. Nguyen
Primary Examiner
Art Unit 1641 6/6/06